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## 510(k) Summary

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**Company:** Arthrex, Inc.  
**Address:** 3050 N. Horseshoe Drive, Naples, FL 33942  
**Phone:** (941) 643-5553  
**Fax:** (941) 643-6218  
**Contact:** Scott M. Durlacher, Regulatory Affairs and Q.A. Manager (ext. 117)

**Trade Name:** Arthrex FASTak Suture Anchor  
**Common Name:** Suture Anchor  
**Classification:** Screw, Fixation, Bone (per 21 CFR 888.3040)

### Description:

The FASTak is a self tapping, threaded anchor with an eyelet for holding suture. The largest suture size used with this device is a single strand of #2. Therefore, in order for the anchor to be effective, it must have a pull-out strength greater than the tensile strength of #2 suture (~ 15 lbs.). The pull-out strength of the FASTak in cortical bone as well as cancellous is at least 38 lbs. and thus provides an acceptable factor of safety. In addition to fulfilling the requirements of a suture anchor, the FASTak also offers the advantage of a self tapping design which eliminates the need for predrilling. In a single motion, the tissue is grasped, shifted and the FASTak inserted. The result is a technique which is both easier and more reproducible.

The FASTak is made of Titanium 6Al-4V alloy (ASTM F136-92). The biocompatibility of this alloy has been well documented.

### Intended Use:

The FASTak Suture Anchor is intended for fixation of suture to bone. This product is intended for use in repairing rotator cuff tears and Bankart lesions.

### Substantial Equivalence:

The Arthrex FASTak Suture Anchor is substantially equivalent to the Mitek GII Anchor. By definition, substantial equivalence means that a device has the same intended use and the same technological characteristics as the predicate device, or **has the same intended use and different technological characteristics, but it can be demonstrated that the device is as safe and effective as the predicate device and does not raise different questions regarding safety and effectiveness from the predicate device.** Our device has the same intended use as the Mitek GII, but different technological characteristics. The GII uses nitinol barbs as the method of fixation, whereas the FASTak has threads. Although there are slight differences in pull-out strength between the two, the critical value is the tensile strength of the suture. Since the pull-out strength of the FASTak is greater than the tensile strength of suture, it fulfills the secondary requirement for substantial equivalence.